Guidance Agenda:
Guidances CDER is Planning to Develop During Calendar Year 2007

(See the Good Guidance Practices (GGPs) regulation on this Web page or 21 CFR 10.115 for details about the Guidance Agenda.)

CATEGORY — Advertising

- Presentation of Risk Information in Prescription Drug and Medical Device

CATEGORY — Chemistry

- Immunogenicity Assessment for Follow-on Protein products
- Immunogenicity Assessment for Therapeutic Protein Products
- Incorporation of Physical-chemical Identifiers (PCID) Into Solid Oral Dosage Form Drug Products for Anticounterfeiting
- Orally Disintegrating Tablets
- Patient Specific Drug Products
- Quality by Design
- Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes

CATEGORY — Clinical/Medical

- Co-packaged Sodium Nitrite and Sodium Thiosulfate Drug Products – Submitting a New Drug Application
- Developing Drug and Biologic Products for the Treatment of Pain
- Developing Drugs to Treat or Prevent Smallpox (Variola) Injection
- Development of Products for the Treatment of Diabetes Mellitus
- Drug Development for the Treatment of Malaria

CATEGORY — Clinical/Pharmacology

- Drug Interaction Studies – Study Design, Data Analysis, and Implications for Dosing and Labeling

CATEGORY — Combination Products

- Drug Diagnostic Co-Development

CATEGORY — Compliance

- Penicillins and Their Definition
- Process Validation: General Principles and Practices
- Testing of Glycerin for Diethylene Glycol

CATEGORY — Drug Safety Information

- Contents of a Complete Submission Package for a Proposed Proprietary Drug or Biologic Name
- Dear Healthcare Professional Letters
- Minimum Data Elements to be Included in a Serious Adverse Event Report for Monograph OTC Products

CATEGORY — Electronic Submissions

- eCTD Location of the ISS & ISE
- Providing Regulatory Submissions in Electronic Format – Analysis Datasets and Documentation
- Providing Regulatory Submissions in Electronic Format – Receipt Date

CATEGORY — Generics

- Individual Product Bioequivalence Recommendations
- Recommendations for Determination of Bioequivalence of Vaginal Antifungal Products
- Recommendations for Stability Data to Support ANDA Submissions and Post Approval Changes

CATEGORY — IND

- Consumer Product Safety Commission – Tamper Resistant Packaging for INDs
- Determining Whether Human Research Studies Can Be Conducted Without An IND

CATEGORY — Labeling

- Content and Format of the Clinical Pharmacology Section
- Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products – Content and Format
- Drug Names and Dosage Forms
- Labeling Dietary Supplements for Women Who Are or Could Be Pregnant
- Labeling for Human Prescription Drug and Biologic Products – Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information

CATEGORY — OTC

- Labeling of Over-the-Counter Skin Protectant Drug Products

CATEGORY — Pharmacology/Toxicology

- Nonclinical Safety Evaluation of Reformulated Drug Products, Including Administration by an Alternate Route

CATEGORY — Procedural

- Assessment of Abuse Potential of Drugs
- Formal Meetings Between CDER Staff and Sponsors
- Target Product Profile – A Strategic Development Process Tool

Note: Agenda items reflect guidances under development as of the date of this posting.